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| 10/646,434      | 08/22/2003  | Gregory James Olsen  | 1171/40069B         | 9168             |

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EXAMINER

LEWIS, AARON J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3743

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding:

# Office Action Summary

Application No.

10/646,434

Applicant(s)

OLSEN ET AL.

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/16/2004 (AMENDMENT).
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-23 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13 and 16-23 is/are rejected.
- 7) ☒ Claim(s) 6, 14 and 15 is/are objected to:
- 8) ☐ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Attachment Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 11/16/2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 10/646,434.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogden et al. ('101).

As to claim 1, Ogden et al. disclose a device for delivering a supply of gases to a user comprising or including: a patient interface (3), adapted to be in fluid communication with said supply (col.5, lines 41-43) of gases and said user in at least a correct orientation and position on said user (col.6, lines 2-4), headgear (13R, 13L, 15R, 15L, 17, 9) adapted to attach to or around the head of said user (fig. 1), and a sliding connection (col.3, lines 30-37, lines 49-55; col.4, lines 20-23, lines 48-58; i.e. detents 39, 41 and 43 slide within channels 45, 47 and 49, respectively) between said headgear and said patient interface.

As to claim 2, Ogden et al. (e.g. fig.1) disclose said patient interface is a nasal mask (3).

As to claim 3, Ogden et al. disclose said nasal mask (3) comprises or includes a body portion having an inlet (12, 20) receiving said supply of gases, and sealing means (5) attached to or integrated with said body portion said sealing means adapted to seal against the facial contours of said user.

As to claim 4, Ogden et al. (col.3, lines 30-37, lines 49-55; col.4, lines 20-23, lines 48-58; i.e. detents 39,41 and 43 slide within channels 45,47 and 49, respectively) disclose said sliding connection adapted to allow said headgear substantial movement with respect to said nasal mask, while still providing compressive force on said sealing means to ensure said supply of gases is delivered to said user without significant leakage (col.6, lines 2-4).

As to claim 5, Ogden et al. (fig.1) disclose said headgear (13R,13L,15R,15L,17,9) comprises or includes a member (9) engaged thereto, said engagement between said headgear and said member adapted to allow temporary release therefrom (i.e. straps (13R,13L,15R,15L,17 are releasably connected to member 9 via slots 27,29,31).

As to claim 7, Ogden et al. disclose said patient interface further comprises or includes at least one restraining means (i.e. channels 45,47,49) on said body portion, in use said member (9) is restrained in at least one axis by, but which can slide easily within at least one other dimension (col.5, lines 27-30), said restraining means and can be easily disengaged therewith (col.5, lines 14-19; the member (9) is expressly disclosed as having a snap fit connection to nasal mask (3)).

As to claim 16, Ogden et al. (fig.1) disclose a nasal mask for delivering gases to a user comprising or including: a body portion (3) having an inlet (12,20), in use said inlet receiving a supply of gases (col.5, lines 41-43), abutting means (5) engaged with said body portion for abutting against the facial contours of said user, and engaging means (channels 45,47,49) for providing a sliding engagement with a means

(13R,13L,15R,15L,17,9) of securement to a user, and a compressive force (from straps 13,15,17) on said abutting means.

As to claim 17, Ogden et al. disclose said engaging means comprises or includes restraining means, said restraining means adapted to in use accommodate an elongate member (9), said restraining means adapted to in use restrain said member in at least one dimension, but allow said member to slide easily within at least one other dimension (col.5, lines 28-30), and providing a compressive force on said abutting means (via straps 13,15), said restraining means adapted to in use easily disengage (col.5, lines 14-19; the member (9) is expressly disclosed as having a snap fit connection to nasal mask (3)) said member (9).

As to claim 18, Ogden et al. disclose a CPAP system (col.5, line 43) for delivering gases to a user comprising or including a pressurized source of gases, a conduit (12,20) in fluid communication with said pressurized source adapted to convey said gases, a patient (3) interface in fluid communication with said conduit in use delivering said gases to said user, and headgear (13R,13L,15R,15L,17,9) attaching said interface with said user the improvement comprising that said patient interface adapted to sliding engage (via channels 45,47,49) with said headgear.

3. Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pate ('917).

As to claim 20, Pate (figs.1,2) disclose a device for delivering a supply of gases to a user comprising or including: a patient interface (11), adapted (18) to be in fluid communication with said supply of gases and said user in at least a correct orientation

and position on said user, and headgear (10) including at least a partial loop (suspension means 12 of figs.1 and 2 forms at least a partial loop around mask 11) adapted to pass across the face of said user.

As to claim 21, Pate discloses said loop (suspension means 12 of figs.1 and 2 forms at least a partial loop around mask 11) adapted to pass over and slidingly engage (via slots 16 and 29) with said interface (11).

As to claim 22, Pate (figs.1 and 2) discloses said loop (suspension means 12 of figs.1 and 2 forms at least a partial loop around mask 11) adapted to pass at least partially through and slidingly engage with said interface (11).

As to claim 23, Pate discloses said loop slides (within slots 16 and 29) in use (e.g. from the configuration illustrated in fig.1 to the configuration illustrated in fig.2 and back again) with respect to said headgear (10).

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden et al. ('101).

The equivalency of patient interfaces in the respiratory art is well known and established practice. That is, the mere substitution of a one patient interface (e.g. a mask for a mouthpiece or a mask for an endotracheal tube would have been an obvious

matter of design choice with no new or unobvious results accruing. Similarly, the mere substitution of a full oral nasal mask for an nasal mask constitutes mere substitution of one mask for another. The interchangeability of these well known patient interfaces would have accomplished the delivery of breathable gases to a patient in an equivalent manner; no one patient interface would have provided the breathable gases to a patient in any manner which would have been superior to another. Finally, a review of the instant specification does not reveal any criticality in the particular patient interface being employed.

As to claim 12, Ogden et al. disclose said headgear includes a low resistance sliding strap slidably connected on, through, adjacent (straps 13,15,17 are slidably connected through slots 27,29,31 of member 9 which is adjacent the patient interface 3) or with said patient interface.

As to claim 13, while Ogden et al. is silent as to the particular material from which straps (13,15,17) are made except to disclose that they are made from flexible and elastic material (col.3, lines 22-24), the particular material can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including polyacetal. Applicant has not attached criticality to the particular material and it is submitted that a material which is both flexible and elastic as disclosed by Ogden et al. would have performed equally to that of a strap made from polyacetal.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden et al. ('101) in view of Mechlenburg et al. ('997).

The difference between Ogden et al. and claim 19 is a humidifier to variably humidify said gases.

Mechlenburg et al. teach the addition of a humidifier (400) to variably humidify breathable gases supplied to a patient in order to prevent drying of such a patient's air passages during therapy (col.6, lines 18-21).

It would have been obvious to modify Ogden et al. to include a humidifier to variably humidify the breathable gases supplied to a patient because it would have prevented drying of such a patient's airways during therapy as taught by Mechlenburg et al..

***Allowable Subject Matter***

7. Claims 6,14,15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

1. Applicant's arguments filed 11/16/2004 have been fully considered but they are not persuasive. Applicant's arguments that Ogden et al. ('101) fail to disclose sliding contact between the headgear and the patient interface are disagreed with because Ogden et al. (fig.7 and col.3, lines 25-55) disclose channels (45,47,49) in which detents (39,41,43) slide as a wearer moves his head as illustrated in fig.7.

Applicant's arguments that Pate ('917) fails to disclose a partial loop adapted to pass across the face of said user based upon the contention that strap (12) constitutes a plurality of straps that are wound on a spool (31) is disagreed with because Pate (col.4, lines 29-43,74-75) discloses a singular strap (12) having two free ends (col.2, lines 38-



44) at least one of which is passed through plural slots (16) and singular slot (30). The length of the strap is effectively shortened or lengthened by rotation of spool (31) thereby providing a wearer with a means for positioning the mask against the face or off the face as illustrated in figs. 1 and 2 of Pate. Strap (12) of Pate (fig.2) is illustrated as passing across the face of user and is readable upon a partial loop (inasmuch as it does not completely encircle a wearer's head). While the spool mechanism of Pate may differ from that of the instant application, the language of the claim does not recite any structural elements that physically distinguish over Pate.

Applicant's arguments regarding claim 13 are noted; however, it is again submitted the particular material can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including polyacetal and inasmuch as applicant has not attached criticality to the particular material and it is submitted that a material which is both flexible and elastic as disclosed by Ogden et al. would have performed equally to that of a strap made from polyacetal.

### ***Conclusion***

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

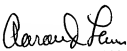
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
February 22, 2005